

07-03-00

A

Practitioner's Docket No. JNJ3-00

PATENT

Preliminary Classification:

Proposed Class: 606Subclass: 198

NOTE: "All applicants are requested to include a preliminary classification on newly filed patent applications. The preliminary classification, preferably class and subclass designations, should be identified in the upper right-hand corner of the letter of transmittal accompanying the application papers, for example 'Proposed Class 2, subclass 129.'" M.P.E.P. § 601, 7th ed.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

JC861 U.S. PTO

09/609163

06/30/00

NEW APPLICATION TRANSMITTAL

Transmitted herewith for filing is the patent application of

Inventor(s): Robert E. Fischell, David R. Fischell, David C. Majercak

WARNING: 37 C.F.R. § 1.41(a)(1) points out:

"(a) A patent is applied for in the name or names of the actual inventor or inventors.

"(1) The inventorship of a nonprovisional application is that inventorship set forth in the oath or declaration as prescribed by § 1.63, except as provided for in § 1.53(d)(4) and § 1.63(d). If an oath or declaration as prescribed by § 1.63 is not filed during the pendency of a nonprovisional application, the inventorship is that inventorship set forth in the application papers filed pursuant to § 1.53(b), unless a petition under this paragraph accompanied by the fee set forth in § 1.17(f) is filed supplying or changing the name or names of the inventor or inventors."

For (title): STENT WITH IMPROVED FLEXIBLE
CONNECTING LINKS

CERTIFICATION UNDER 37 C.F.R. § 1.10*

(Express Mail label number is mandatory.)

(Express Mail certification is optional.)

I hereby certify that this New Application Transmittal and the documents referred to as attached therein are being deposited with the United States Postal Service on this date June 30, 2000, in an envelope as "Express Mail Post Office to Addressee," mailing Label Number EL350795182 US, addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

Robert E. Fischell

(type or print name of person mailing paper)

Robert E. Fischell

Signature of person mailing paper

WARNING: Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. § 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.

WARNING: Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. § 1.10(b).

"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

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JC468 U.S. PTO
06/30/00

09/609163-003000

1. Type of Application

This new application is for a(n)

(check one applicable item below)

- ☒ Original (nonprovisional)
- ☐ Design
- ☐ Plant

WARNING: Do not use this transmittal for a completion in the U.S. of an International Application under 35 U.S.C. § 371(c)(4), unless the International Application is being filed as a divisional, continuation or continuation-in-part application.

WARNING: Do not use this transmittal for the filing of a provisional application.

NOTE: If one of the following 3 items apply, then complete and attach **ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF A PRIOR U.S. APPLICATION CLAIMED** and a **NOTIFICATION IN PARENT APPLICATION OF THE FILING OF THIS CONTINUATION APPLICATION**.

- ☐ Divisional.
- ☒ Continuation.
- ☐ Continuation-in-part (C-I-P).

2. Benefit of Prior U.S. Application(s) (35 U.S.C. §§ 119(e), 120, or 121)

NOTE: A nonprovisional application may claim an invention disclosed in one or more prior filed copending nonprovisional applications or copending international applications designating the United States of America. In order for a nonprovisional application to claim the benefit of a prior filed copending nonprovisional application or copending international application designating the United States of America, each prior application must name as an inventor at least one inventor named in the later filed nonprovisional application and disclose the named inventor's invention claimed in at least one claim of the later filed nonprovisional application in the manner provided by the first paragraph of 35 U.S.C. § 112. Each prior application must also be:

(i) An international application entitled to a filing date in accordance with PCT Article 11 and designating the United States of America; or

(ii) Complete as set forth in § 1.51(b); or

(iii) Entitled to a filing date as set forth in § 1.53(b) or § 1.53(d) and include the basic filing fee set forth in § 1.16; or

(iv) Entitled to a filing date as set forth in § 1.53(b) and have paid therein the processing and retention fee set forth in § 1.21(f) within the time period set forth in § 1.53(f).

37 C.F.R. § 1.78(a)(1).

NOTE: If the new application being transmitted is a divisional, continuation or a continuation-in-part of a parent case, or where the parent case is an International Application which designated the U.S., or benefit of a prior provisional application is claimed, then check the following item and complete and attach **ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED**.

WARNING: If an application claims the benefit of the filing date of an earlier filed application under 35 U.S.C. §§ 120, 121 or 365(c), the 20-year term of that application will be based upon the filing date of the earliest U.S. application that the application makes reference to under 35 U.S.C. §§ 120, 121 or 365(c). (35 U.S.C. § 154(a)(2) does not take into account, for the determination of the patent term, any application on which priority is claimed under 35 U.S.C. §§ 119, 365(a) or 365(b).) For a c-i-p application, applicant should review whether any claim in the patent that will issue is supported by an earlier application and, if not, the applicant should consider canceling the reference to the earlier filed application. The term of a patent is not based on a claim-by-claim approach. See Notice of April 14, 1995, 60 Fed. Reg. 20,195, at 20,205.

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WARNING: When the last day of pendency of a provisional application falls on a Saturday, Sunday, or Federal holiday within the District of Columbia, any nonprovisional application claiming benefit of the provisional application must be filed prior to the Saturday, Sunday, or Federal holiday within the District of Columbia. See 37 C.F.R. § 1.78(a)(3).

- ☐ The new application being transmitted claims the benefit of prior U.S. application(s). Enclosed are ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

3. Papers Enclosed

A. Required for filing date under 37 C.F.R. § 1.53(b) (Regular) or 37 C.F.R. § 1.153 (Design) Application

17 Pages of specification

1 Pages of claims

7 Sheets of drawing

WARNING: DO NOT submit original drawings. A high quality copy of the drawings should be supplied when filing a patent application. The drawings that are submitted to the Office must be on strong, white, smooth, and non-shiny paper and meet the standards according to § 1.84. If corrections to the drawings are necessary, they should be made to the original drawing and a high-quality copy of the corrected original drawing then submitted to the Office. Only one copy is required or desired. For comments on proposed then-new 37 C.F.R. § 1.84, see Notice of March 9, 1988 (1990 O.G. 57-62).

NOTE: "Identifying indicia, if provided, should include the application number or the title of the invention, inventor's name, docket number (if any), and the name and telephone number of a person to call if the Office is unable to match the drawings to the proper application. This information should be placed on the back of each sheet of drawing a minimum distance of 1.5 cm. (5/8 inch) down from the top of the page . . ." 37 C.F.R. § 1.84(c)).

(complete the following, if applicable)

- ☐ The enclosed drawing(s) are photograph(s), and there is also attached a "PETITION TO ACCEPT PHOTOGRAPH(S) AS DRAWING(S)." 37 C.F.R. § 1.84(b).
- ☐ formal
- ☐ informal

B. Other Papers Enclosed

2 Pages of declaration and power of attorney

1 Pages of abstract

___ Other

4. Additional papers enclosed

- ☒ Amendment to claims
- ☒ Cancel in this applications claims 2 - 30 before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.)
- ☒ Add the claims shown on the attached amendment. (Claims added have been numbered consecutively following the highest numbered original claims.)
- ☒ Preliminary Amendment
- ☐ Information Disclosure Statement (37 C.F.R. § 1.98)
- ☐ Form PTO-1449 (PTO/SB/08A and 08B)
- ☐ Citations

(The declaration or oath, along with the surcharge required by 37 C.F.R. § 1.16(e) can be filed subsequently).

- ☐ Showing that the filing is authorized.
(not required unless called into question. 37 C.F.R. § 1.41(d))

6. Inventorship Statement

WARNING: If the named inventors are each not the inventors of all the claims an explanation, including the ownership of the various claims at the time the last claimed invention was made, should be submitted.

The inventorship for all the claims in this application are:

- ☒ The same.

or

- ☐ Not the same. An explanation, including the ownership of the various claims at the time the last claimed invention was made,
☐ is submitted.
☐ will be submitted.

7. Language

NOTE: An application including a signed oath or declaration may be filed in a language other than English. An English translation of the non-English language application and the processing fee of \$130.00 required by 37 C.F.R. § 1.17(k) is required to be filed with the application, or within such time as may be set by the Office. 37 C.F.R. § 1.52(d).

- ☒ English
☐ Non-English
☐ The attached translation includes a statement that the translation is accurate. 37 C.F.R. § 1.52(d).

8. Assignment

- ☐ An assignment of the invention to _____

☐ is attached. A separate ☐ "COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING NEW PATENT APPLICATION" or ☐ FORM PTO 1595 is also attached.
☒ will follow.

NOTE: "If an assignment is submitted with a new application, send two separate letters—one for the application and one for the assignment." Notice of May 4, 1990 (1114 O.G. 77-78).

WARNING: A newly executed "CERTIFICATE UNDER 37 C.F.R. § 3.73(b)" must be filed when a continuation-in-part application is filed by an assignee. Notice of April 30, 1993, 1150 O.G. 62-64.

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9. Certified Copy

Certified copy(ies) of application(s)

Country	Appln. No.	Filed
Country	Appln. No.	Filed
Country	Appln. No.	Filed

from which priority is claimed

- ☐ is (are) attached.
☐ will follow.

NOTE: The foreign application forming the basis for the claim for priority must be referred to in the oath or declaration. 37 C.F.R. § 1.55(a) and 1.63.

NOTE: This item is for any foreign priority for which the application being filed directly relates. If any parent U.S. application or International Application from which this application claims benefit under 35 U.S.C. § 120 is itself entitled to priority from a prior foreign application, then complete item 18 on the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

10. Fee Calculation (37 C.F.R. § 1.16)**A. ☒ Regular application**

CLAIMS AS FILED			
Number filed	Number Extra	Rate	Basic Fee 37 C.F.R. § 1.16(a) \$760.00
Total Claims (37 C.F.R. § 1.16(c))	2 - 20 = 0	× \$ 18.00	0
Independent Claims (37 C.F.R. § 1.16(b))	1 - 3 = 0	× \$ 78.00	0
Multiple dependent claim(s), if any (37 C.F.R. § 1.16(d))		+ \$260.00	

- ☐ Amendment cancelling extra claims is enclosed.
☐ Amendment deleting multiple-dependencies is enclosed.
☐ Fee for extra claims is not being paid at this time.

NOTE: If the fees for extra claims are not paid on filing they must be paid or the claims cancelled by amendment, prior to the expiration of the time period set for response by the Patent and Trademark Office in any notice of fee deficiency. 37 C.F.R. § 1.16(d).

Filing Fee Calculation

\$ 760.00

B. ☐ Design application
(\$310.00—37 C.F.R. § 1.16(f))

Filing Fee Calculation

\$

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- C. ☐ Plant application
(\$480.00—37 C.F.R. § 1.16(g))

Filing fee calculation

\$ _____

11. Small Entity Statement(s)

- ☐ Statement(s) that this is a filing by a small entity under 37 C.F.R. § 1.9 and 1.27 is (are) attached.

WARNING: "Status as a small entity must be specifically established in each application or patent in which the status is available and desired. Status as a small entity in one application or patent does not affect any other application or patent, including applications or patents which are directly or indirectly dependent upon the application or patent in which the status has been established. The refiling of an application under § 1.53 as a continuation, division, or continuation-in-part (including a continued prosecution application under § 1.53(d)), or the filing of a reissue application requires a new determination as to continued entitlement to small entity status for the continuing or reissue application. A nonprovisional application claiming benefit under 35 U.S.C. § 119(e), 120, 121, or 365(c) of a prior application, or a reissue application may rely on a statement filed in the prior application or in the patent if the nonprovisional application or the reissue application includes a reference to the statement in the prior application or in the patent or includes a copy of the statement in the prior application or in the patent and status as a small entity is still proper and desired. The payment of the small entity basic statutory filing fee will be treated as such a reference for purposes of this section." 37 C.F.R. § 1.28(a)(2).

WARNING: "Small entity status must not be established when the person or persons signing the . . . statement can unequivocally make the required self-certification." M.P.E.P., § 509.03, 6th ed., rev. 2, July 1996 (emphasis added).

(complete the following, if applicable)

- ☐ Status as a small entity was claimed in prior application
_____ / _____, filed on _____, from which benefit
is being claimed for this application under:

35 U.S.C. § ☐ 119(e),
☐ 120,
☐ 121,
☐ 365(c),

and which status as a small entity is still proper and desired.

- ☐ A copy of the statement in the prior application is included.

Filing Fee Calculation (50% of A, B or C above)

\$ _____

NOTE: Any excess of the full fee paid will be refunded if small entity status is established and a refund request are filed within 2 months of the date of timely payment of a full fee. The two-month period is not extendable under § 1.136. 37 C.F.R. § 1.28(a).

12. Request for International-Type Search (37 C.F.R. § 1.104(d))

(complete, if applicable)

- ☐ Please prepare an international-type search report for this application at the time when national examination on the merits takes place.

13. Fee Payment Being Made at This Time

☐ Not Enclosed

☐ No filing fee is to be paid at this time.

(This and the surcharge required by 37 C.F.R. § 1.16(e) can be paid subsequently.)

☒ Enclosed

☒ Filing fee

\$ 760.00

☐ Recording assignment

(\$40.00; 37 C.F.R. § 1.21(h))

(See attached "COVER SHEET FOR
ASSIGNMENT ACCOMPANYING NEW
APPLICATION".)

\$ _____

☐ Petition fee for filing by other than all the
inventors or person on behalf of the inventor
where inventor refused to sign or cannot be
reached

(\$130.00; 37 C.F.R. §§ 1.47 and 1.17(l))

\$ _____

☐ For processing an application with a
specification in

a non-English language

(\$130.00; 37 C.F.R. §§ 1.52(d) and 1.17(k))

\$ _____

☐ Processing and retention fee

(\$130.00; 37 C.F.R. §§ 1.53(d) and 1.21(l))

\$ _____

☐ Fee for international-type search report

(\$40.00; 37 C.F.R. § 1.21(e))

\$ _____

NOTE: 37 C.F.R. § 1.21(f) establishes a fee for processing and retaining any application that is abandoned for failing to complete the application pursuant to 37 C.F.R. § 1.53(f) and this, as well as the changes to 37 C.F.R. §§ 1.53 and 1.78(a)(1), indicate that in order to obtain the benefit of a prior U.S. application, either the basic filing fee must be paid, or the processing and retention fee of § 1.21(f) must be paid, within 1 year from notification under § 53(f).

Total fees enclosed

\$ _____

14. Method of Payment of Fees

☒ Check in the amount of \$ 760.00

☐ Charge Account No. _____ in the amount of
\$ _____

A duplicate of this transmittal is attached.

NOTE: Fees should be itemized in such a manner that it is clear for which purpose the fees are paid. 37 C.F.R. § 1.22(b).

15. Authorization to Charge Additional Fees

WARNING: If no fees are to be paid on filing, the following items should not be completed.

WARNING: Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges, if extra claim charges are authorized.

- ☐ The Commissioner is hereby authorized to charge the following additional fees by this paper and during the entire pendency of this application to Account No. _____.

- ☐ 37 C.F.R. § 1.16(a), (f) or (g) (filing fees)
☐ 37 C.F.R. § 1.16(b), (c) and (d) (presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 C.F.R. § 1.16(d)), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.

- ☐ 37 C.F.R. § 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application)
☐ 37 C.F.R. § 1.17(a)(1)–(5) (extension fees pursuant to § 1.136(a)).
☐ 37 C.F.R. § 1.17 (application processing fees)

NOTE: ". . . A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under § 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in § 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R. § 1.136(a)(3).

- ☐ 37 C.F.R. § 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 C.F.R. § 1.311(b))

NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 C.F.R. § 1.311(b).

NOTE: 37 C.F.R. § 1.28(b) requires "Notification of any change in status resulting in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying, . . . the issue fee. . . ." From the wording of 37 C.F.R. § 1.28(b), (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

16. Instructions as to Overpayment

NOTE: "... Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. § 1.26(a).

- ☐ Credit Account No. _____
- ☐ Refund



SIGNATURE OF PRACTITIONER

ROBERT E. FISCHELL

(type or print name of attorney)

14600 VIBURNUM DRIVE

P.O. Address

DAYTON, MARYLAND 21036

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Reg. No. --

Tel. No. (301) 854-0606

Customer No.

☒ **Incorporation by reference of added pages**

(check the following item if the application in this transmittal claims the benefit of prior U.S. application(s) (including an international application entering the U.S. stage as a continuation, divisional or C-I-P application) and complete and attach the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED)

- ☒ **Plus Added Pages for New Application Transmittal Where Benefit of Prior U.S. Application(s) Claimed**

Number of pages added 5

- ☐ **Plus Added Pages for Papers Referred to in Item 4 Above**

Number of pages added _____

- ☐ **Plus added pages deleting names of inventor(s) named in prior application(s) who is/are no longer inventor(s) of the subject matter claimed in this application.**

Number of pages added _____

- ☐ **Plus "Assignment Cover Letter Accompanying New Application"**

Number of pages added _____

- ☐ **Statement Where No Further Pages Added**

(if no further pages form a part of this Transmittal, then end this Transmittal with this page and check the following item)

- ☐ **This transmittal ends with this page.**

ADDED PAGES FOR APPLICATION TRANSMITTAL WHERE BENEFIT OF
PRIOR U.S. APPLICATION(S) CLAIMED

NOTE: See 37 C.F.R. § 1.78.

17. Relate Back

WARNING: If an application claims the benefit of the filing date of an earlier filed application under 35 U.S.C. §§ 120, 121 or 365(c), the 20-year term of that application will be based upon the filing date of the earliest U.S. application that the application makes reference to under 35 U.S.C. §§ 120, 121 or 365(c). (35 U.S.C. § 154(a)(2) does not take into account, for the determination of the patent term, any application on which priority is claimed under 35 U.S.C. §§ 119, 365(a) or 365(b).) For a c-i-p application, applicant should review whether any claim in the patent that will issue is supported by an earlier application and, if not, the applicant should consider canceling the reference to the earlier filed application. The term of a patent is not based on a claim-by-claim approach. See Notice of April 14, 1995, 60 Fed. Reg. 20,195, at 20,205.

(complete the following, if applicable)

☒ Amend the specification by inserting, before the first line, the following sentence: *

A. 35 U.S.C. § 119(e).

NOTE: "Any nonprovisional application claiming the benefit of one or more prior filed copending provisional applications must contain or be amended to contain in the first sentence of the specification following the title a reference to each such prior provisional application, identifying it as a provisional application, and including the provisional application number (consisting of series code and serial number)." 37 C.F.R. § 1.78(a)(4).

☐ "This application claims the benefit of U.S. Provisional Application(s) No(s).:

APPLICATION NO(S):

FILING DATE

____ / _____

____ "

____ / _____

____ "

____ / _____

____ "

(Added Pages for Application Transmittal Where Benefit of Prior U.S. Application(s) Claimed
[4-1.1]—page 1 of 5)

* Please see p.1 of the continuing application.

B. 35 U.S.C. §§ 120, 121 and 365(c)

NOTE: "Except for a continued prosecution application filed under § 1.53(d), any nonprovisional application claiming the benefit of one or more prior filed copending nonprovisional applications or international applications designating the United States of America must contain or be amended to contain in the first sentence of the specification following the title a reference to each such prior application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. . . . Cross-references to other related applications may be made when appropriate." (See § 1.14(a)). 37 C.F.R. § 1.78(a)(2).

- ☒ "This application is a
☒ continuation
☐ continuation-in-part
☐ divisional

of copending application(s)

- ☒ application number 09/ 192,101 filed on 11/13/98 "
☐ International Application _____ filed on _____
_____ and which designated the U.S."

NOTE: The proper reference to a prior filed PCT application that entered the U.S. national phase is the U.S. serial number and the filing date of the PCT application that designated the U.S.

NOTE: (1) Where the application being transmitted adds subject matter to the International Application, then the filing can be as a continuation-in-part or (2) if it is desired to do so for other reasons then the filing can be as a continuation.

NOTE: The deadline for entering the national phase in the U.S. for an international application was clarified in the Notice of April 28, 1987 (1079 O.G. 32 to 46) as follows:

"The Patent and Trademark Office considers the International application to be pending until the 22nd month from the priority date if the United States has been designated and no Demand for International Preliminary Examination has been filed prior to the expiration of the 19th month from the priority date and until the 32nd month from the priority date if a Demand for International Preliminary Examination which elected the United States of America has been filed prior to the expiration of the 19th month from the priority date, provided that a copy of the international application has been communicated to the Patent and Trademark Office within the 20 or 30 month period respectively. If a copy of the international application has not been communicated to the Patent and Trademark Office within the 20 or 30 month period respectively, the international application becomes abandoned as to the United States 20 or 30 months from the priority date respectively. These periods have been placed in the rules as paragraph (h) of § 1.494 and paragraph (i) of § 1.495. A continuing application under 35 U.S.C. 365(c) and 120 may be filed anytime during the pendency of the international application."

- ☐ "The nonprovisional application designated above, namely application _____ / _____, filed _____, claims the benefit of U.S. Provisional Application(s) No(s).:

APPLICATION NO(S).:

FILING DATE

_____ / _____	_____ "
_____ / _____	_____ "
_____ / _____	_____ "

- ☐ Where more than one reference is made above, please combine all references into one sentence.

18. Relate Back—35 U.S.C. § 119 Priority Claim for Prior Application

The prior U.S. application(s), including any prior International Application designating the U.S., identified above in item 17B, in turn itself claim(s) foreign priority(ies) as follows:

Country	Appln. no.	Filed on
The certified copy(ies) has (have)		
<input type="checkbox"/> been filed on _____, in prior application 0 / _____, which was filed on _____		
<input type="checkbox"/> is (are) attached.		

WARNING: *The certified copy of the priority application that may have been communicated to the PTO by the International Bureau may not be relied on without any need to file a certified copy of the priority application in the continuing application. This is so because the certified copy of the priority application communicated by the International Bureau is placed in a folder and is not assigned a U.S. serial number unless the national stage is entered. Such folders are disposed of if the national stage is not entered. Therefore, such certified copies may not be available if needed later in the prosecution of a continuing application. An alternative would be to physically remove the priority documents from the folders and transfer them to the continuing application. The resources required to request transfer, retrieve the folders, make suitable record notations, transfer the certified copies, enter and make a record of such copies in the Continuing Application are substantial. Accordingly, the priority documents in folders of international applications that have not entered the national stage may not be relied on. Notice of April 28, 1987 (1079 O.G. 32 to 46).*

19. Maintenance of Copendency of Prior Application

NOTE: *The PTO finds it useful if a copy of the petition filed in the prior application extending the term for response is filed with the papers constituting the filing of the continuation application. Notice of November 5, 1985 (1060 O.G. 27).*

A. ☐ Extension of time in prior application

(This item must be completed and the papers filed in the prior application, if the period set in the prior application has run.)

- ☐ A petition, fee and response extends the term in the pending prior application until _____
- ☐ A copy of the petition filed in prior application is attached.

B. ☐ Conditional Petition for Extension of Time in Prior Application

(complete this item, if previous item not applicable)

- ☐ A conditional petition for extension of time is being filed in the pending prior application.
- ☐ A copy of the conditional petition filed in the prior application is attached.

20. Further Inventorship Statement Where Benefit of Prior Application(s) Claimed

(complete applicable item (a), (b) and/or (c) below)

- (a) ☒ This application discloses and claims only subject matter disclosed in the prior application whose particulars are set out above and the inventor(s) in this application are

☒ the same.

- ☐ less than those named in the prior application. It is requested that the following inventor(s) identified for the prior application be deleted:

(type name(s) of inventor(s) to be deleted)

- (b) ☐ This application discloses and claims additional disclosure by amendment and a new declaration or oath is being filed. With respect to the prior application, the inventor(s) in this application are

☐ the same.

- ☐ the following additional inventor(s) have been added:

(type name(s) of inventor(s) to be added)

- (c) The inventorship for all the claims in this application are

☒ the same.

- ☐ not the same. An explanation, including the ownership of the various claims at the time the last claimed invention was made

☐ is submitted.

☐ will be submitted.

21. Abandonment of Prior Application (if applicable)

- ☐ Please abandon the prior application at a time while the prior application is pending, or when the petition for extension of time or to revive in that application is granted, and when this application is granted a filing date, so as to make this application copending with said prior application.

NOTE: According to the Notice of May 13, 1983 (103, TMOG 6-7), the filing of a continuation or continuation-in-part application is a proper response with respect to a petition for extension of time or a petition to revive and should include the express abandonment of the prior application conditioned upon the granting of the petition and the granting of a filing date to the continuing application.

22. Petition for Suspension of Prosecution for the Time Necessary to File an Amendment

WARNING: "The claims of a new application may be finally rejected in the first Office action in those situations where (A) the new application is a continuing application of, or a substitute for, an earlier application, and (B) all the claims of the new application (1) are drawn to the same invention claimed in the earlier application, and (2) would have been properly finally rejected on the grounds of art of record in the next Office action if they had been entered in the earlier application." M.P.E.P., § 706.07(b), 7th ed.

NOTE: Where it is possible that the claims on file will give rise to a first action final for this continuation application and for some reason an amendment cannot be filed promptly (e.g., experimental data is being gathered) it may be desirable to file a petition for suspension of prosecution for the time necessary.

(check the next item, if applicable)

- ☐ There is provided herewith a Petition To Suspend Prosecution for the Time Necessary to File An Amendment (New Application Filed Concurrently)

23. Small Entity (37 C.F.R. § 1.28(a))

- ☐ Applicant has established small entity status by the filing of a statement in parent application /_____ on _____.
☐ A copy of the statement previously filed is included.

WARNING: See 37 C.F.R. § 1.28(a).

WARNING: "Small entity status must not be established when the person or persons signing the . . . statement can unequivocally make the required self-certification." M.P.E.P., § 509.03, 7th ed. (emphasis added).

24. NOTIFICATION IN PARENT APPLICATION OF THIS FILING

- ☒ A notification of the filing of this
(check one of the following)

- ☒ continuation
☐ continuation-in-part
☐ divisional

Is being filed in the parent application, from which this application claims priority under 35 U.S.C. § 120.

(Added Pages for Application Transmittal Where Benefit of Prior U.S. Application(s) Claimed
[4-1.1]—page 5 of 5)

A

07-03-00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Washington, D.C. 20231

06/30/00
Jc498 U.S. PRO

Docket: JNJ3-00

Examiner: V.Q. Bui

In re application of: Robert Fischell, et al

Art Unit: 3731

Serial No.:

Filed:

For: STENT WITH IMPROVED FLEXIBLE CONNECTING LINKS

PRELIMINARY AMENDMENT

Hon. Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Applicants, by the undersigned inventor, hereby submit a Preliminary Amendment being files concurrently and together with a Continuation Patent Application which is a Continuation of parent case Serial 09/192,101, referenced above. Please amend the Continuation Patent Application as follows:

IN THE CLAIMS:

Please cancel Claims 1-30 without prejudice and without disclaiming any of the subject matter contained therein.

Please insert the following claims:

31. A stent in the form of a thin-walled, multi-cellular, tubular structure having a longitudinal axis, the stent comprising:

a multiplicity of sets of strut members, each set of strut members being longitudinally separated each from the other and each set of strut members forming a closed, ring-like cylindrical section of the stent, each set of strut members consisting of a multiplicity of strut elements, each strut element consisting of one curved end strut that is joined at a junction point to one diagonal strut with each junction point being an end point of each curved end strut and each curved end strut having two end points and a center point that is centered between the two end points; and

a multiplicity of sets of flexible links with each set of flexible links connecting two of the multiplicity of sets of strut members, each set of flexible links consisting of a multiplicity of individual flexible links, each individual flexible link being a single undulating structure that extends generally in the longitudinal direction that is parallel to the stent's longitudinal axis and each individual flexible link having two ends, each one of the two ends being fixedly attached to one curved end strut of the multiplicity of strut elements, each flexible link having a link width as measured in a direction that is generally along the surface of the stent and a link wall thickness that is measured in a radial direction from the stent's longitudinal axis, the ratio of the link width to the link thickness being less than one.

32. The stent of claim 25 wherein the ratio of the link width to the link thickness is less than 0.8.

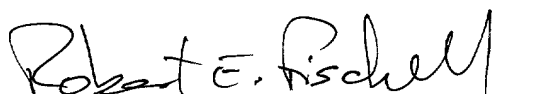
REMARKS

This Preliminary Amendment is being filed concurrent and together with a Continuation Application having parent Application Serial No. 09/192,101 with a filing date of November 13, 1998.

By this Amendment, Claims 1-30 of the parent case have been canceled and newly inserted Claims 31 and 32 are provided for prosecution.

It is now believed that this Continuation Patent Application has been placed in condition for examination, and such action is respectfully requested.

Respectfully submitted,



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Date: June 30, 2000

STENT WITH IMPROVED FLEXIBLE CONNECTING LINKS

This is continuation of application Serial No. 09/192,101 filed November 13, 1998.

FIELD OF USE

The present invention is an expandable stent for insertion into a vessel of a human body for the purpose of creating and maintaining the patency of that vessel.

BACKGROUND

In U.S. Patent 5,697,971 Fischell et al describe a balloon expandable stainless steel vascular stent with two different cell types. Cells containing an "H"-shaped link to provide strength and cells having an "S"-shaped link to provide increased flexibility and the ability to "unjail" side branch arteries. In addition, "S" links of the Fischell, et al invention attach to the strut members at the center of the end of the end struts. This increases the length of the "S" link along the longitudinal axis of the stent as compared with off-center attachment points. Finally, the "H" link of the Fischell et al prior art stent increases the relative strength of the section of the stent where it is used by shortening the distance between adjacent sets of strut members as compared to the distance between adjacent strut members for the "S" links.

SUMMARY OF INVENTION

The current invention is a comparatively thick-walled vascular stent comprising sets of strut members connected by flexible links. This design uses a script "N" shaped flexible link instead of the "S" link described by Fischell et al in U.S. Patent 5,697,971. The "N" links, instead of touching or overlapping during crimping, are designed to nest one into the other, allowing the stent to be both thick-walled and to crimp down without overlap onto a low profile balloon. The "N" links are attached to the strut members not at the center like the "S" links in the prior art, but off center near the end of the curved end strut portion of each strut member. This off center attachment point allows for a more flexible

link without increasing the cell size of the expanded stent. Small cell size is desirable to limit plaque prolapse into the lumen of the expanded stent. It is also desirable to replace the "H" link described by Fischell et al in the prior art with a short "J"-shaped, flexible link that will keep the struts close together for strength but unlike the "H" link will not detract from the stent's flexibility. To enhance flexibility, the wire width of the "N" and "J" links should be less than 0.10 mm. The relatively thin strut width with thick wall allows the "J" and "N" links to easily lengthen and shorten during stent delivery into the body while still allowing the stent to retain a considerable degree of radial strength.

An alternative embodiment of the flexible thick-walled stent has also been envisioned where the "N" link has certain curved segments to further minimize stent cell size. It is also conceived to increase flexibility by using "M"-shaped or "W"-shaped links each having additional undulations as compared to the "N" link.

Thus an object of this invention is to have a multi-cell, thick-walled stent with at least two different types of closed perimeter cells where every cell includes at least one longitudinally extending flexible link.

Another object of this invention is to have a stent with flexible links designed to nest inside each other when the stent is crimped down onto the balloon of a balloon catheter so as to reduce the stent profile (i.e., to reduce the outer diameter).

Another object of this invention is to have a stent with flexible links having the shapes of a "J", inverted "J", an "N", inverted "N", a sine wave, "M" or "W".

Another object of this invention is to have a stent with flexible links that are attached off center to the curved ends of the strut members.

Still another objective of this invention is to have a multi-cell stent with short flexible links forming the part of the perimeter of one type of cell and longer flexible links forming part of the perimeter of a second type of cell.

Still another objective of this invention is to have a thick-walled stent with "N" shaped links where two of the three vertical segments of the "N" are curved to minimize the longitudinal extent of the link and thus minimize cell size for the expanded stent.

Still another object of this invention is to have flexible links between sets of strut members where the ratio of link width to link wall thickness is less than 1.0.

Still another object of this invention is to have the struts at the ends of the stent be of a shorter length as compared to struts at a central location so as to enhance the radial strength at the ends of the stent.

Still another objective of this invention is to have a stent in which the sets of strut members are constructed from several connected arcs of different radii with no straight segments.

Still another objective of this invention is to have a stent adapted for implantation at the ostium of a vessel, the stent having an extremely flexible distal section and a less flexible proximal section, the proximal section being radially stronger than the distal section after stent expansion to its nominal diameter.

These and other important objects and advantages of this invention will become apparent from the detailed description of the invention and the associated drawings provided herein.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 a flat, layout, 2-dimensional plan view of a prior art cylindrical stent in its pre-deployed state.

FIG. 2 illustrates one embodiment of the present invention represented as a flat, layout, 2-dimensional plan view of a multi-cell cylindrical stent in its pre-deployed state.

FIG. 3 is a 3-dimensional, perspective view of a flexible "N" link of the stent shown in FIG. 2.

FIG. 4 shows a flat, layout, 2-dimensional plan view of the cylindrical stent of FIG. 2 as it would appear after deployment.

FIG. 5 illustrates another embodiment of the present invention having an alternative arrangement of the "N" and "J" links between sets of strut members, represented as a flat, layout, 2-dimensional plan view.

FIG. 6 illustrates another embodiment of the present invention having a single type of flexible connecting link with the stent being represented by a flat, layout, 2-dimensional plan view.

FIG. 7 illustrates another embodiment of the present invention which has flexible sine wave links having curved segments to allow closer spacing of the sets of strut members thereby producing a relative reduction in post-expansion cell size and increase in stent radial rigidity.

FIG. 8 illustrates still another embodiment of the present invention having the flexible sine wave links of FIG. 7 for connecting the end pairs of sets of strut members with "M" or "W" shaped links to connect centrally located sets of strut members.

FIG. 9 illustrates an embodiment of the present stent invention adapted for implantation at the ostium of a vessel, the stent being shown as a flat, layout, 2-dimensional plan view; the proximal section of the stent having only "J" links and the distal section having only flexible sine wave links.

DETAILED DESCRIPTION OF THE INVENTION

FIG. 1 shows a prior art stent 1 as it would appear if it were cut longitudinally and then laid out into a flat, 2-dimensional configuration. It should be clearly understood that the stent 1 is in fact cylindrical in shape, which cylindrical shape would be obtained by rolling the flat configuration of FIG. 1 into a cylinder with the top points "A" joined to the bottom points "B". The stent 1 is typically fabricated by laser machining of a thin-walled, cylindrical, stainless steel tube.

The stent 1 has exactly two different types of cells: namely, structural cells 7 and special expandable cells 5. Both these cells are formed from end struts 3 and diagonal struts 8. The horizontal "H" links 6 form part of the perimeter of the cells 7. The undulating "S" links 4 form part of the perimeter of the expandable cells 5. Within the dotted lines of FIG. 1 is a set of strut members 2, which is a closed, ring-like, cylindrical segment of the stent 1 consisting of a set of connected end struts 3 and diagonal struts 8. The stent 1 also has adjacent sets of strut members 2 that are connected either by multiple "H" links 6 or by multiple "S" links 4. A limitation of the prior art stent 1 is that in crimping the stent 1 down to the small diameters associated with low profile balloons on balloon delivery catheters, the top 9 of one "S" link 4 will come into contact with the bottom 11 of the "S" link 4 that is situated just above the "S" link 4. This may either limit the ability of the stent 1 to crimp further down when the "S" links 4 touch, or will cause the "S" links 4 to overlap. In thin-walled stents with wall thickness less than 0.08 mm, it may be acceptable for the "S" links to overlap, but as wall thickness increases to 0.10 mm and beyond, overlapping is much less acceptable. This is because the overlapped struts will increase the outside diameter (i.e., the profile) of the non-deployed stent as crimped onto a balloon. In stents of wall thickness of 0.12 mm (known to be a wall thickness for stainless steel stents that provides good radiopacity under fluoroscopy), it is desirable to have a flexible link with a shape that will not touch or overlap as the stent is crimped down on low profile balloons.

The rigid "H" link 6 of the stent 1 which is designed to reduce the separation of adjacent sets of strut members 2 for increased radial strength, limits the flexibility of the stent 1 and the ability of each set of strut members 2 to expand independently.

FIG. 2 illustrates one embodiment of the present invention which is the stent 10 in its crimped, pre-deployed state as it would appear if it were cut longitudinally and then laid out into a flat, 2-dimensional configuration. It should be clearly understood that the stent 10 is in fact cylindrical in shape, which cylindrical shape would be obtained by rolling the flat configuration of FIG. 2 into a cylinder with the top points "C" joined to the bottom points "D". The stent 10 is typically fabricated by laser machining of a cylindrical, stainless steel tube.

A set of strut members 12 (as shown within the dotted rectangle 12) is a closed, cylindrical, ring-like section of the stent 10 comprising six pairs of longitudinally separated curved end struts 13 connected by diagonal struts 18. Although the set of strut members 12 consists of twelve curved end struts 13 connected to twelve diagonal struts 18, it is envisioned that embodiments of the present invention stent can be constructed using sets of strut members with as few as eight curved end struts 13 with eight diagonal struts 18, or as many as twenty-four curved end struts 13 with as many as twenty-four diagonal struts 18. The set of strut members can be said to consist of a multiplicity of strut elements with each strut element consisting of one curved end strut 13 joined to one diagonal strut 18.

Except at the extreme ends of the stent, every curved end strut 13 is attached to a connecting link that is either an "N" link 14 or a "J" link 16.

A stent 10 that is thus fully connected is called a "closed cell" stent. Another way to describe the fully connected configuration of the stent 10 is as multiple longitudinally spaced sets of strut members 12 inter-connected by either sets of flexible "N" links 24 or sets of flexible "J" links 26. Each set of flexible "N" links 24 comprising multiple circumferentially spaced "N" links 14 with each "N" link 14 being connected to two

curved end struts 13 of adjacent sets of strut members 12. The number of "N" links 14 in the set of "N" links 24 is one-half of the total number of curved end struts 13 in the set of strut members 12. Each set of flexible "J" links 26 consists of multiple circumferentially spaced "J" links 16 with each "J" link being connected to two curved end struts 13 of the adjacent sets of strut members 12. The number of "J" links 16 in the set of "J" links 26 is one half of the total number of curved end struts 13 in the set of strut members 12.

As seen in FIG. 2, each "N" link 14 consists of four generally longitudinally extending curved segments 21B connected by three generally straight circumferentially extending segments 19B. Each "J" link 16 consists of two generally longitudinally extending curved segments 21A connected by a straight circumferential segment 19A.

The stent 10 can be described as having adjacent sets of strut members 12 that are connected either by multiple "N" links 14 or by multiple "J" links 16. Each "N" link 14 is shaped so as to nest together into the adjacent "N" link 14 as is clearly seen in FIG. 2. "Nesting" is defined as having the top of a first flexible link inserted beyond the bottom of a second flexible link that is situated just above that first flexible link and the bottom of that first flexible link is inserted just below the top of a third flexible link that is situated just below that first flexible link. Thus, a stent with nested individual flexible links has each individual flexible link nested into both adjacent flexible links; i.e., the flexible link directly below and the flexible link directly above that individual flexible link. This nesting permits crimping of the stent 10 to smaller diameters than the prior art stent 1 of FIG. 1 without having the "N" links 14 overlap. In the embodiment of FIG. 2, the curved end struts 13 of the sets of strut members 12 are designed so that they touch as shown in FIG. 2 when the adjacent flexible links 14 or 16 are nested within each other.

The pre-deployed stent 10 bends easily as it goes around curved arteries because the "N" links 14 can easily lengthen on the outside of the bent stent and shorten on the inside of the bent stent. Each curved end strut 13 of FIG. 2 is shaped like a half-annulus with an arc center 51 and two ends 45. The attachment point 55 for the "N" link 14 to the curved end strut 13 is not at the center point 51 of the curved end strut 13 but at a location

between the center point 51 and the end point 45 of the curved end strut 13. This allows each and every generally circumferential segment 19B of the "N" links 14 to be made longer than if the attachment point was near the center point 51 of the curved end struts 13. The longer the circumferential segment 19B of the "N" link 14, the more lever arm will be available to allow flexure of the "N" link 14. This provides improved stent flexibility that is an advantage of this design. It should be noted that the circumferential segments 19B are all of approximately the same length. It should also be noted that each end point 45 of the curved end strut 13 is the junction point where each diagonal strut 18 is joined to each curved end strut 13.

By replacing the "H" link 6 of the prior art stent 1 of FIG. 1 with the "J" link 16 of FIG. 2, there is enough flexure between the sets of strut members 12 connected by the "J" links 16 to permit each to expand independently. The "J" links 16 serve the same purpose as the "H" links 6 of FIG. 1. That purpose being to fully connect adjacent sets of strut members 12 so that the adjacent sets of strut members 12 are longitudinally close to one another thus providing smaller expanded cells and increased radial strength to each end of the stent. Each "J" link 16 has two longitudinally extending curved segments 21A that are joined to one generally circumferentially extending segment 19A.

FIG. 3 is a 3-dimensional, perspective view of the flexible "N" link 14 of the stent 10 of FIG. 2. As seen in FIGS. 2 and 3, the "N" link 14 comprises four generally longitudinally extending curved segments 21B connected by three generally circumferentially extending segments 19B with each "N" link 14 having two ends that are identically the attachment point 55 where the "N" link 14 connects to the curved end strut 13. The "N" link 14 shown in FIG. 3 has a strut width 15 as measured in a direction that is generally along the surface of the stent that is smaller than the wall thickness 25 as measured in a radial direction from the stent's longitudinal axis 28. The strut width 15 for a coronary stent should be less than 0.10 mm to provide good flexibility while the wall thickness 25 should be greater than 0.10 mm to provide good stent radiopacity. Ideally the ratio of the width 15 to the thickness 25 should be less than 1.0 and preferably less than 0.8. For a coronary stent, the nominal strut width 15 would typically be 0.08

mm and the nominal wall thickness 25 would typically be 0.12 mm. The combination of thin strut width 15 and thick wall thickness 25 will allow the "N" link 14 to easily lengthen and shorten for increased stent flexibility while making the "N" link 14 relatively stiff with respect to bulging inward into the lumen of the stent 10. This stiffness will enhance the ability of the "N" link 14 to push outward against plaque in a coronary artery after the stent 10 is deployed. In addition to improved flexibility, the thin width 15 of the "N" link 14 will allow it to stretch during stent expansion to reduce the foreshortening of the stent 10.

FIG. 4 is a 2-dimensional representation of the cylindrical stent 10' after deployment; i.e., after radially outward expansion. It should be clearly understood that the stent 10' is in fact cylindrical in shape, which cylindrical shape would be obtained by rolling the flat configuration of FIG. 4 into a cylinder with the top points "C' " joined to the bottom points "D' ". FIG. 4 shows how the stent 10 of FIG. 2 would appear after expansion. FIG. 4 also shows the deployed structural cells 36 having on their perimeter two of the "J" links 16 and the deployed special expandable cells 34 having on their perimeter two of the flexible "N" links 14.

It should be noted that circumferentially extending sets of cells 34 and 36 are formed into ring-like, circumferential, cylindrical sections with (in this case) exactly six cells per cylindrical segment. Typically a multi-cell stent would have at least three cells per circumferential cylindrical section. The stent 10' has exactly two cylindrical sections 37 of structural cells 36 and four cylindrical sections 35 of expandable cells 34.

Prior to deployment, the "N" links 14 of the stent 10 of FIG. 2 provide greatly enhanced longitudinal flexibility for the stent 10. This allows for easier placement of the stent 10 through highly curved coronary arteries.

FIGS. 2 and 4 clearly show that the "J" link 16 is much shorter in length as compared to the "N" link 14. Therefore, the perimeter length of the cells 34 is longer than the perimeter length of the cells 36. Therefore, as compared to a cell 36, not only is it easier

to expand a cell 34 by placing a balloon through that cell for side branch access and inflating that balloon to a high pressure, but each cell 34 is also expandable to a greater diameter as compared to any cell 36. Since only the center section of the stent 10' would be placed over the ostium of an arterial side branch, "J" links 16 are used only between the end pairs of sets of strut members 12'. Having structural cells 36 at the ends of the stent 10' will increase the radial strength of the stent 10' at the ends. This has merit because the ends of a stent tend to be weaker than the center as the sets of strut members 12' at the end of the stent 10' are connected to only one adjacent set of strut members 12'. Having expandable cells 34 in the central region (with each cell having a longer perimeter length) of the stent will allow use of a second balloon to create an opening in the stent 10' at the site of a stent side branch.

FIG. 5 shows the stent 20 which is another embodiment of the present invention in its crimped, pre-deployed state as it would appear if it were cut longitudinally and then laid out into a flat, 2-dimensional configuration. The stent 20 like the stent 10 of FIG. 2 has curved end struts 13 and diagonal struts 18 with each set of strut members 12 connected by sets of flexible links 19, 24 or 27. In this embodiment, three different types of flexible links are used. A set of "N" links 24 comprising six circumferentially spaced "N" links 14 and a set of inverted "N" links 27 comprising six circumferentially spaced inverted "N" links 17 each connect to adjacent sets of strut members 12 at the ends of the stent 20. A set of inverted "J" links 29 comprising six circumferentially spaced inverted "J" links 19 are used to connect the adjacent sets of strut members 12 in the center of the stent 20. The shape of the "N" links 14 and inverted "N" links 17 facilitate the links' ability to lengthen and shorten as the stent bends around a curve during delivery into the human body. This ability to lengthen and shorten helps to prevent the sets of strut members from being pushed or pulled off the balloon during delivery into the body and is particularly applicable to short stents which tend to have relatively poor stent retention onto an inflatable balloon. The stent 20 with its greater strength at its central region would advantageously be used for comparatively short stenoses that have a tough, calcified central section. It should also be understood that a regular "J" link could be used for the stent 20 in place of the inverted "J" link 19.

FIG. 6 shows yet another embodiment of the present invention which is a stent 30 in its crimped, pre-deployed state as it would appear if it were cut longitudinally and then laid out into a flat, 2-dimensional configuration. The stent 30 comprises end sets of strut members 32 located at each end of the stent 30 and three center sets of strut members 12 connected each to the other by sets of flexible "N" links 24. The end sets of strut members 32 consist of curved end struts 33 and diagonal struts 39. The center sets of strut members 12 located longitudinally between the end sets of strut members 32 consist of curved end struts 13 and diagonal struts 18. One curved end strut (such as the curved end strut 13) that is joined at a junction point to one diagonal strut (such as the diagonal strut 18) is defined herein as a strut element (such as the strut element 38 of FIG. 6). In this embodiment, the diagonal struts 39 of the end sets of strut members 32 are shorter in length than the diagonal struts 18 of the central sets of strut members 12. The shorter diagonal struts 39 will increase the post-expansion strength of the end sets of strut members 32 as compared with the central sets of strut members 12. The stent 30 also differs from the stent 10 of FIG. 1 and the stent 20 of FIG. 3 in that all of the adjacent sets of strut members 32 or 12 are connected with "N" links 14. The stent 30 has no "J" links 16 as shown in the stent 10 of FIG. 2. Also as shown in FIG. 2, each "N" link 14 has three generally circumferentially extending segments 19 that run in an approximately circumferential direction. When crimped onto a balloon, a stent's ability to avoid sliding on the balloon is related to the ratio of circumferentially placed metal segments to longitudinally extending segments. The three circumferentially extending segments 19 of the "N" link 14 provide a significant amount of circumferentially placed metal to assist in stent retention. In addition, the end set of strut members 32 will stay crimped down on a balloon even as the balloon catheter is repeatedly advanced around a sharp bend because the "N" links 14 can easily lengthen and shorten to adjust the stent length on the outside and inside of the bend respectively.

FIG. 7 shows the stent 40 which is still another embodiment of the present invention. The stent 40 is shown in its crimped, pre-deployed state as it would appear if it were cut longitudinally and then laid out into a flat, 2-dimensional configuration. It should be

clearly understood that the stent 40 is in fact cylindrical in shape, which cylindrical shape would be obtained by rolling the flat configuration of FIG. 7 into a cylinder with the top points "E" joined to the bottom points "F". The stent 40 is typically fabricated by laser machining of a cylindrical, stainless steel tube.

A central set of strut members 42 is a cylindrical, closed, ring-like section of the stent 40 consisting of six pairs of longitudinally separated curved end struts 43 connected by curved diagonal struts 48. Each of the curved diagonal struts 48 has two connected curved segments 48A and 48B that are fixedly attached at an inflection point 48C. A curved diagonal 48 has an advantage over a straight diagonal 18 (of FIG. 2) because, for the expansion of the stent to the same diameter into an artery, the strain in the metal of each set of strut members is reduced. Every curved end strut 43 of a central set of strut members 42 is attached to either a connecting link which is an sine wave link 44 or a curved "J" link 46. The stent 40 also has two end sets of strut members 52 comprising six pairs of longitudinally separated curved end struts 53 connected by curved diagonal struts 58. The central set of strut members 42 is situated longitudinally between the two end sets of strut members 52. Each of the two end sets of strut members 52 is joined to a central set of strut members 42 by a multiplicity of individual curved "J" links 46. Each central set of strut members 42 is joined to an adjacent central set of strut members 42 by a multiplicity of individual sine wave links 44. In this embodiment, half of the curved end struts 53 of the end set of strut members 52 are attached to the curved "J" links 46, the other half of the curved end struts 53 are at the extreme ends of the stent 40. The stent 40 has curved diagonal struts 58 of the end sets of strut members 52 that are shorter than the curved diagonal struts 48 of the central sets of strut members 42. Shorter diagonal struts enhance the post-expansion radial strength of the end sets of strut members 52 as compared to the central sets of strut members 42. This is desirable as the end sets of strut members 52 are only connected to adjacent sets of strut members 42 on one side.

As seen in FIG. 7, the sine wave links 44 consist of a set of four generally longitudinally extending curved segments 41 at the top and bottom, a straight circumferential section 49 at the center and two curved circumferential segments 47 which run parallel to the curved

end struts 43 of the sets of strut members 42. The stent 40 differs from the stent 10 of FIG. 2 as the sine wave links 44 of the stent 40 replaces the three generally straight circumferential segments 19B of the "N" link 14 of the stent 10 with two curved circumferential segments 47 and one generally straight segment 49. Use of the curved circumferential segments 47 creates a reduced longitudinal separation of the adjacent sets of strut members 42 connected by the sine wave links 44 as compared to the separation of the sets of strut members 12 connected by the "N" links 14 of FIG. 2. A reduced longitudinal separation of adjacent sets of strut members 42 will result in a smaller expanded cell size for the stent 40 as compared to the stent 10, all other dimensions being equal. This provides slightly increased radial rigidity when the stent 40 is deployed because there are more sets of strut members 42 per unit length of the stent 40 as compared with the number of sets of strut members 12 of the stent 10. The curved circumferential segments 47 are designed to allow the laser used in cutting the stent 40 the minimum slot width between the outside of the curved strut 43 and the inside of the thin curved section 47. The curved "J" links 46 of the stent 40 also have a similar curved shape parallel to the curved struts 43 or the curved struts 53.

The stent 60 shown in FIG. 8 is a flat layout of an ultra-flexible embodiment of the present invention shown in its crimped pre-deployed state as it would appear if it were cut longitudinally and then laid out into a flat, 2-dimensional configuration. It should be clearly understood that the stent 60 is in fact cylindrical in shape, which cylindrical shape would be obtained by rolling the flat configuration of FIG. 8 into a cylinder with the top points "G" joined to the bottom points "H". The stent 60 is typically fabricated by laser machining of a cylindrical, stainless steel tube.

A central set of strut members 62 is a cylindrical, closed, ring-like section of the stent 60 consists of a set of connected, curved end struts 63 and curved diagonal struts 68. Every curved end strut 63 of a central set of strut members 62 is attached to a connecting link which is either a flexible "M" link 64 or a "W" link 84. The stent 60 also has two end sets of strut members 72 consisting of a set of connected, curved end struts 73 and curved diagonal struts 78. In this embodiment, half of the curved end struts 73 of the end set of

strut members 72 are attached to sine wave links 44, the other half of the curved end struts 73 are at the extreme ends of the stent 60. The curved diagonal struts 78 of the end sets of strut members 72 are shorter than the curved diagonal struts 68 of the central sets of strut members 62. Shorter diagonal struts enhance the post-expansion radial strength of the end sets of strut members 72 as compared to the central sets of strut members 62. This is desirable as the end sets of strut members 72 are only connected to adjacent sets of strut members 62 on one side and are therefore naturally weaker.

Each sine wave link 44 of the stent 60 has four curved longitudinally extending segments 41, two curved circumferentially extending segments 47 and one generally straight circumferentially extending segment 49.

The stent 60 has two sets of flexible links 74 each consisting of six individual flexible "M" links 64. The "M" links 64 consist of a set of five generally longitudinally extending curved segments 61 at the top and bottom, two generally straight circumferentially extending segments 69 in the center and two curved circumferentially extending segments 67 which run parallel to the curved end struts 63 of the sets of strut members 62. The stent 60 differs from the stent 40 of FIG. 7 in that the "M" links 64 of the stent 60 have one more generally longitudinally extending curved segment 61 and one more generally straight circumferential segment 69 as compared to the sine wave links 44 of the stent 40.

The stent 60 has two sets of flexible links 94 each consisting of six individual flexible links "W" links 84. The "W" links 84 comprise a set of five generally longitudinally extending curved segments 81 at the top and bottom, two generally straight circumferential segments 89 in the center and two curved circumferentially extending segments 87 which run generally parallel to the curved end struts 63 of the sets of strut members 62. The "W" link 84 is the mirror image of the "M" link 64. It is obvious that any flexible link described herein could be connected at the center of any of the curved end segments of the set of strut members that are described herein.

The stent 90 of FIG. 9 is still another embodiment of the present invention shown in its crimped pre-deployed state as it would appear if it were cut longitudinally and then laid out into a flat, 2-dimensional configuration. The stent 90 is adapted to be placed at the ostium of a vessel of the human body such as a renal artery. The stent 90 has a proximal section 94 and a distal section 95. The proximal section 94 is constructed from five shortened sets of strut members 92 connected by sets of flexible curved "J" links 96. Each set of strut members 92 consists of six pairs of curved end struts 93 connected by curved diagonal struts 98. Each set of flexible curved "J" links 96 consists of six circumferentially spaced curved "J" links 46 identical to the "J" links 46 of the stent 40 of FIG. 7.

The distal section 95 of the stent 90 is constructed from three sets of strut members 42 connected by sets of flexible sine wave links 99. Each set of strut members 42 consists of six pairs of curved end struts 43 connected by curved diagonal struts 48. Each set of flexible sine wave links 99 consists of six circumferentially spaced sine wave links 44 identical to the sine wave links 44 of the stent 40 of FIG. 7.

The distal section 95 of the stent 90 will be more longitudinally flexible than the proximal section 94 because of the presence of the sine wave links 44. After being deployed, the proximal section 94 will be radially stronger than the distal section 95 for two reasons. First, the proximal section 94 has five strong sets of strut members 92 over approximately the same longitudinal length as the three sets of strut members 42 of the distal section 95. Second, each strong set of strut members 92 has shorter curved diagonals 98 as compared to the curved diagonals 48 of the sets of strut members 42. Shorter diagonals produce increased radial strength for a deployed stent. It should be understood that the proximal section 94 that would be placed near the ostium of an artery should have greater radial strength to prevent the ostium from closing. Also, the distal section 95 should have increased flexibility so as to more easily make the turn to enter the ostium of a vessel such as the renal artery.

Although the descriptions herein show individual, flexible “J”, curved “J”, “M”, “N”, “W” and sine wave links in specific configurations, it is envisioned that any combination of these flexible links or inverted flexible links can be utilized. Similarly, although end sets of strut members having shorter diagonals have been shown in FIGS. 6, 7 and 8, it is envisioned that sets of strut members having shorter diagonals might be used at any position along the length of the stent. It is also envisioned that any of the individual flexible links described herein could be connected to a center point of the adjacent curved end strut. For example, in FIG. 2, the attachment point 55 at the end of the “N” link 14 could be connected to the center point 51 of the curved end strut 13.

Although the stents described herein would principally be used in arteries, they could also be applied to other types of vessels of the human body such as veins, vascular graphs, bronchial tubes in the lung or the bile duct in the liver.

To clearly define the various shapes of the flexible links that are single, undulating structures that extend generally in a longitudinal direction, the following definitions shall apply:

1. “J” link: a generally longitudinally extending flexible structure having two generally longitudinally extending curved segments that are joined by one circumferentially extending segment as shown by element 16 of FIGS. 2 and 4
2. Inverted “J” link: the mirror image of the “J” link defined in 1 above as shown by element 19 of FIG. 5.
3. “N” link: a generally longitudinally extending flexible structure having four generally longitudinally extending curved segments that are joined by three generally straight circumferentially extending segments of approximately equal length; as shown by the element 14 of FIGS. 2, 3, 4, 5, and 6

4. Inverted "N" link. the mirror image of the "N" link as defined in 3 above; as shown by element 17 of FIG. 5.
5. Sine-wave link: a flexible link that has two curved generally circumferentially extending end segments and one generally straight circumferentially extending segment that is situated between the curved segments instead of the three generally straight circumferentially extending segments of the "N" link. The sine wave link is illustrated as element 44 of FIGS. 7, 8 and 9.
6. "M" link: a generally longitudinally extending flexible structure having five generally longitudinally extending curved segments that are connected together by four generally circumferentially extending segments of approximately equal length; as shown by element 64 of FIG. 8.
7. "W" link: same as 6 above except it is turned upside down; as shown by element 84 of FIG. 8.

Various other modifications, adaptations, and alternative designs are of course possible in light of the above teachings. Therefore, it should be understood at this time that within the scope of the appended claims, the invention can be practiced otherwise than as specifically described herein.

What is claimed is:

1. A stent in the form of a thin-walled, multi-cellular, tubular structure having a longitudinal axis, the stent comprising:

a multiplicity of sets of strut members, each set of strut members being longitudinally separated each from the other and each set of strut members forming a closed, ring-like cylindrical section of the stent, each set of strut members consisting of a multiplicity of strut elements, each strut element consisting of one curved end strut that is joined at a junction point to one diagonal strut with each junction point being an end point of each curved end strut and each curved end strut having two end points and a center point that is centered between the two end points; and

a multiplicity of sets of flexible links with each set of flexible links connecting two of the multiplicity of sets of strut members, each set of flexible links consisting of a multiplicity of individual flexible links, each individual flexible link being a single undulating structure that extends generally in the longitudinal direction that is parallel to the stent's longitudinal axis and each individual flexible link having two ends, each one of the two ends being fixedly attached to one curved end strut of the multiplicity of strut elements at an attachment point situated between the center and one end of the curved end strut.

2. The stent of claim 1 wherein at least some of the individual flexible links are "J" links.
3. The stent of claim 1 wherein at least some of the individual flexible links are inverted "J" links.

4. The stent of claim 1 wherein at least some of the individual flexible links are "N" links.
5. The stent of claim 1 wherein at least some of the individual flexible links are inverted "N" links.
6. The stent of claim 1 wherein at least some of the individual flexible links are "M" links.
7. The stent of claim 1 wherein at least some of the individual flexible links are "W" links.
8. The stent of claim 1 wherein at least some of the individual flexible links are sine wave links.
9. The stent of claim 1 wherein each individual flexible link has an adjacent flexible link located on each side of the individual flexible link, and each individual flexible link is nested into both adjacent flexible links.
10. The stent of claim 1 wherein at least one of the generally longitudinally extending flexible links has a curved, generally circumferentially extending segment with the curve being generally parallel to an adjacent curved end strut of the multiplicity of strut elements.
11. The stent of claim 10 wherein at least one of the generally circumferentially extending segments is a generally straight segment.
12. The stent of claim 1 wherein the diagonal strut of at least one strut element has two curved segments that are joined at an inflection point.

13. The stent of claim 1 wherein a first set of strut members is an end set of strut members with one end set of strut members being situated at each end of the stent and a second set of strut members is a central set of strut members that is situated longitudinally between the end sets of strut members and the length of the diagonal struts of each of the two end sets of strut members of the stent is shorter than the length of the diagonal struts of the central sets of strut members.

14. A stent in the form of a thin-walled, multi-cellular, tubular structure having a longitudinal axis, the stent comprising:

a multiplicity of sets of strut members, each set of strut members being longitudinally separated each from the other and each set of strut members forming a closed, ring-like cylindrical section of the stent, each set of strut members consisting of a multiplicity of strut elements, each strut element consisting of one curved end strut that is joined at a junction point to one diagonal strut with each junction point being an end point of each curved end strut and each curved end strut having two end points and a center point that is centered between the two end points; and

at least one set of flexible links of a first type and at least one set of flexible links of a second type, each one of the two types of sets of flexible links being connected to two of the multiplicity of sets of strut members, each set of flexible links consisting of a multiplicity of individual flexible links, each individual flexible link being a single undulating structure that extends generally in the longitudinal direction that is parallel to the stent's longitudinal axis and each individual flexible link having two ends, each one of the two ends being fixedly attached to one curved end strut of the multiplicity of strut elements.

15. The stent of claim 14 wherein the stent has one end set of strut members located at each end of the stent and at least one central set of strut members situated

longitudinally there between, each of the two end sets of strut members being joined to a central set of strut members by a multiplicity of individual flexible "J" links.

16. The stent of claim 14 wherein the stent has one end set of strut members located at each end of the stent and at least one central set of strut members situated longitudinally there between, each of the two end sets of strut members being joined to a central set of strut members by a multiplicity of individual flexible inverted "J" links.
17. The stent of claim 14 wherein the stent has one end set of strut members located at each end of the stent and at least one central set of strut members situated longitudinally there between, each of the two end sets of strut members being joined to a central set of strut members by a multiplicity of individual flexible "N" links.
18. The stent of claim 14 wherein the stent has one end set of strut members located at each end of the stent and at least one central set of strut members situated longitudinally there between, each of the two end sets of strut members being joined to a central set of strut members by a multiplicity of individual flexible inverted "N" links.
19. The stent of claim 14 wherein the stent has one end set of strut members located at each end of the stent and at least one central set of strut members situated longitudinally there between, each of the two end sets of strut members being joined to a central set of strut members by a multiplicity of individual flexible sine wave links.
20. The stent of claim 14 wherein the stent has one end set of strut members at each end of the stent and at least two central sets of strut members situated longitudinally there between, each central set of strut members being joined to an

adjacent central set of strut members by a multiplicity of individual flexible "N" links.

21. The stent of claim 14 wherein the stent has one end set of strut members at each end of the stent and at least two central sets of strut members situated longitudinally there between, each central set of strut members being joined to an adjacent central set of strut members by a multiplicity of individual flexible inverted "N" links.
22. The stent of claim 14 wherein the stent has one end set of strut members at each end of the stent and at least two central sets of strut members situated longitudinally there between, each central set of strut members being joined to an adjacent central set of strut members by a multiplicity of individual flexible "M" links.
23. The stent of claim 14 wherein the stent has one end set of strut members at each end of the stent and at least two central sets of strut members situated longitudinally there between, each central set of strut members being joined to an adjacent central set of strut members by a multiplicity of individual flexible "W" links.
24. The stent of claim 14 wherein the stent has one end set of strut members at each end of the stent and at least two central sets of strut members situated longitudinally there between, each central set of strut members being joined to an adjacent central set of strut members by a multiplicity of individual flexible sine wave links.

25. A stent in the form of a thin-walled, multi-cellular, tubular structure having a longitudinal axis, the stent comprising:

a multiplicity of sets of strut members, each set of strut members being longitudinally separated each from the other and each set of strut members forming a closed, ring-like cylindrical section of the stent, each set of strut members consisting of a multiplicity of strut elements, each strut element consisting of one curved end strut that is joined at a junction point to one diagonal strut with each junction point being an end point of each curved end strut and each curved end strut having two end points and a center point that is centered between the two end points; and

a multiplicity of sets of flexible links with each set of flexible links connecting two of the multiplicity of sets of strut members, each set of flexible links consisting of a multiplicity of individual flexible links, each individual flexible link being a single undulating structure that extends generally in the longitudinal direction that is parallel to the stent's longitudinal axis and each individual flexible link having two ends, each one of the two ends being fixedly attached to one curved end strut of the multiplicity of strut elements, each flexible link having a link width as measured in a direction that is generally along the surface of the stent and a link wall thickness that is measured in a radial direction from the stent's longitudinal axis, the ratio of the link width to the link thickness being less than one.

26. The stent of claim 25 wherein the ratio of the link width to the link thickness is less than 0.8.

27. A stent in the form of a thin-walled, multi-cellular, tubular structure having a longitudinal axis, the stent comprising:

a multiplicity of sets of strut members, each set of strut members being longitudinally separated each from the other and each set of strut members forming a closed, ring-like cylindrical section of the stent, each set of strut members consisting of a multiplicity of strut elements, each strut element consisting of one curved end strut that is joined at a junction point to one diagonal strut with each junction point being an end point of each curved end strut and each curved end strut having two end points and a center point that is centered between the two end points; and

a multiplicity of sets of flexible links with each set of flexible links connecting two of the multiplicity of sets of strut members, the multiplicity of sets of flexible links including a first set of flexible links consisting of a multiplicity of individual first flexible links, each individual first flexible link being a single undulating structure that extends generally in the longitudinal direction that is parallel to the stent's longitudinal axis, each individual first flexible link having at least two generally longitudinally extending curved segments and at least one generally circumferentially extending segment, and a second set of flexible links, each of the second set of flexible links including individual second flexible links, each individual second flexible link having at least four generally longitudinally extending curved segments and at least three generally circumferentially extending segments that are of approximately equal length.

28. The stent of claim 27 wherein the individual second flexible links are "M" links.

29. The stent of claim 27 wherein the individual second flexible links are "W" links.

30. The stent of claim 27 wherein the individual second flexible links have at least one circumferentially extending segment with a curved shape, the curve of the circumferentially extending segment being generally parallel to the curve of its adjacent curved end strut of the multiplicity of strut elements.

ABSTRACT

Disclosed is a stent that has flexible connecting links that have a strut width as measured in a direction that is generally along the surface of the stent that is smaller than the wall thickness of the stent as measured in a radial direction from the stent's longitudinal axis. The strut width for a coronary stent should be less than 0.10 mm to provide good flexibility while the wall thickness should be greater than 0.10 mm to provide good stent radiopacity. Ideally the ratio of the width to the thickness should be less than 1.0 and preferably less than 0.08 mm and the nominal wall thickness would typically be 0.12 mm. The combination of thin strut width and thick wall thickness will allow the flexible link to easily lengthen and shorten for increased stent flexibility while making the link relatively stiff with respect to bulging inward into the lumen of the stent. This stiffness enhances the ability of the link to push outward against plaque in a coronary artery after the stent is deployed. In addition to improved flexibility, the thin width of the flexible links allow them to stretch during stent expansion thus reducing foreshortening of the deployed stent.

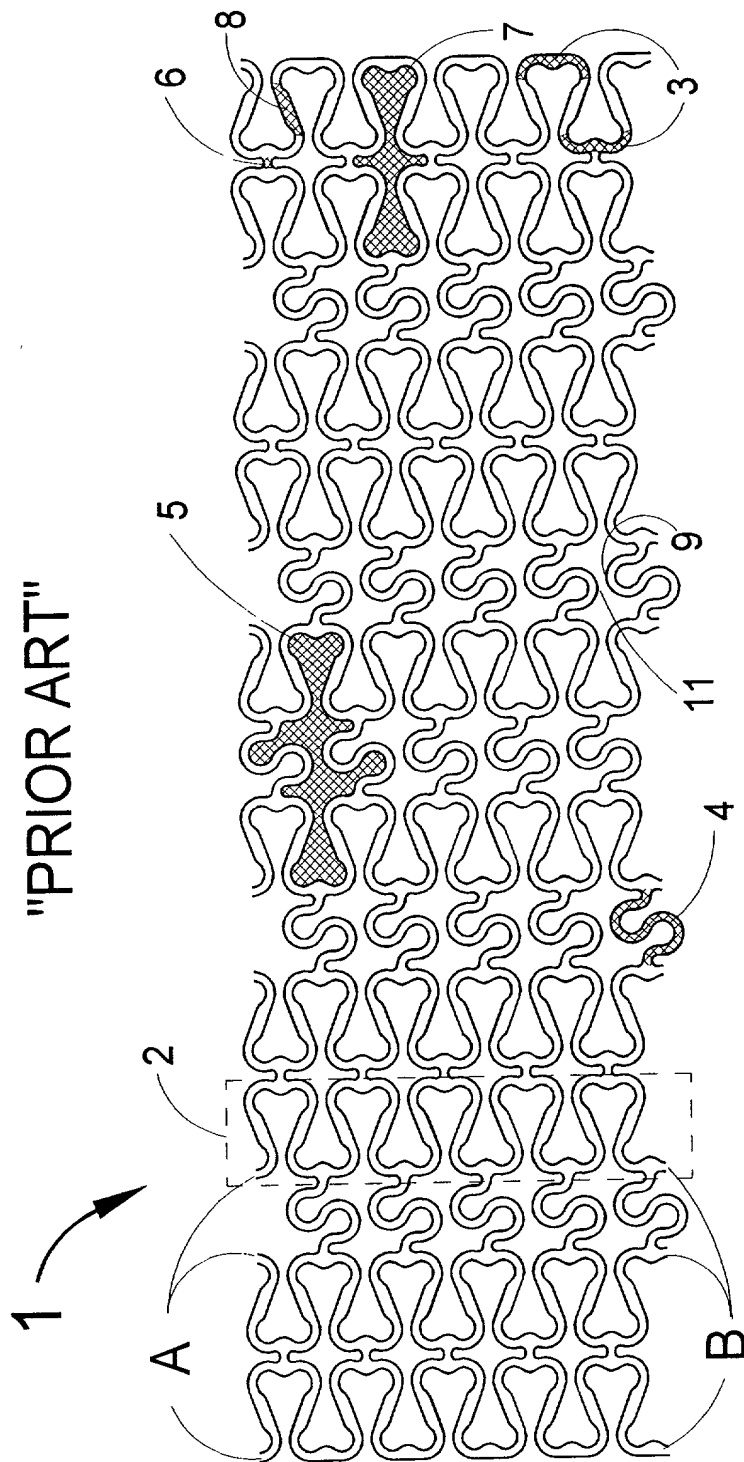
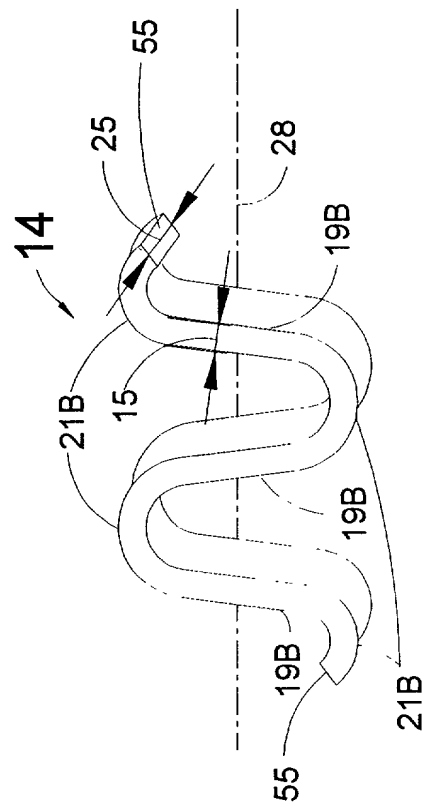
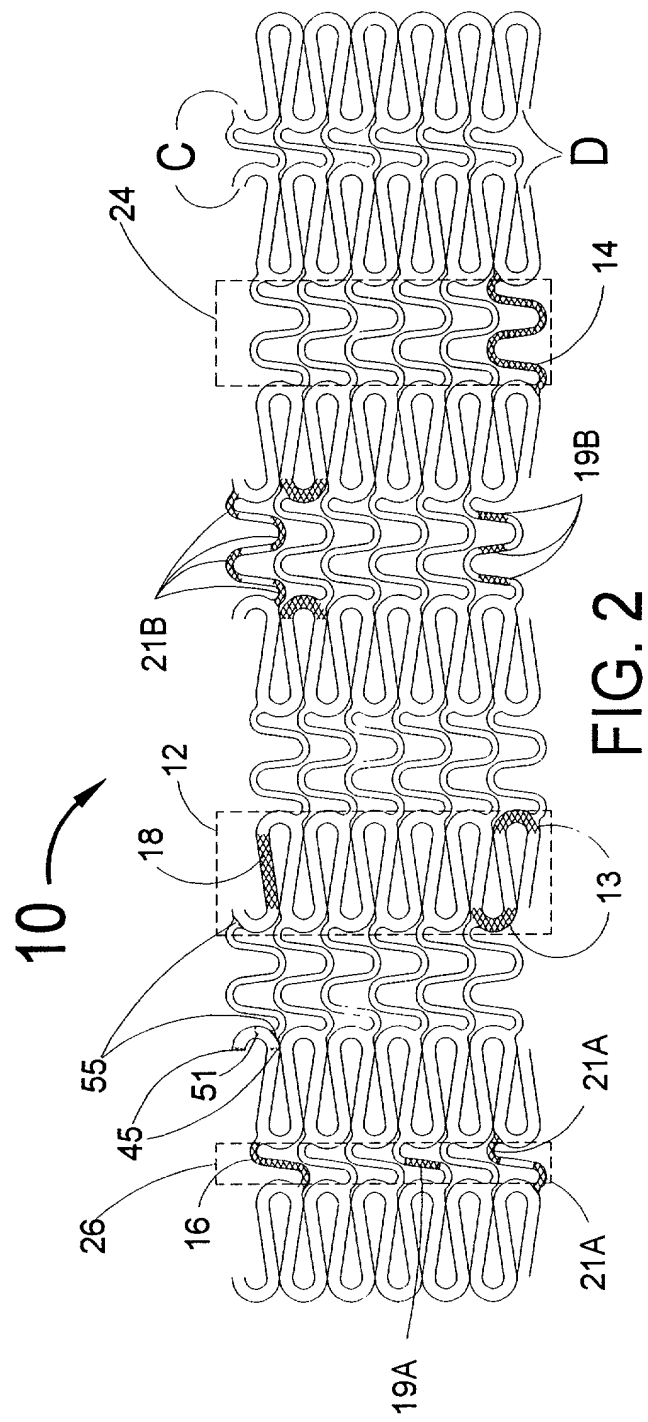
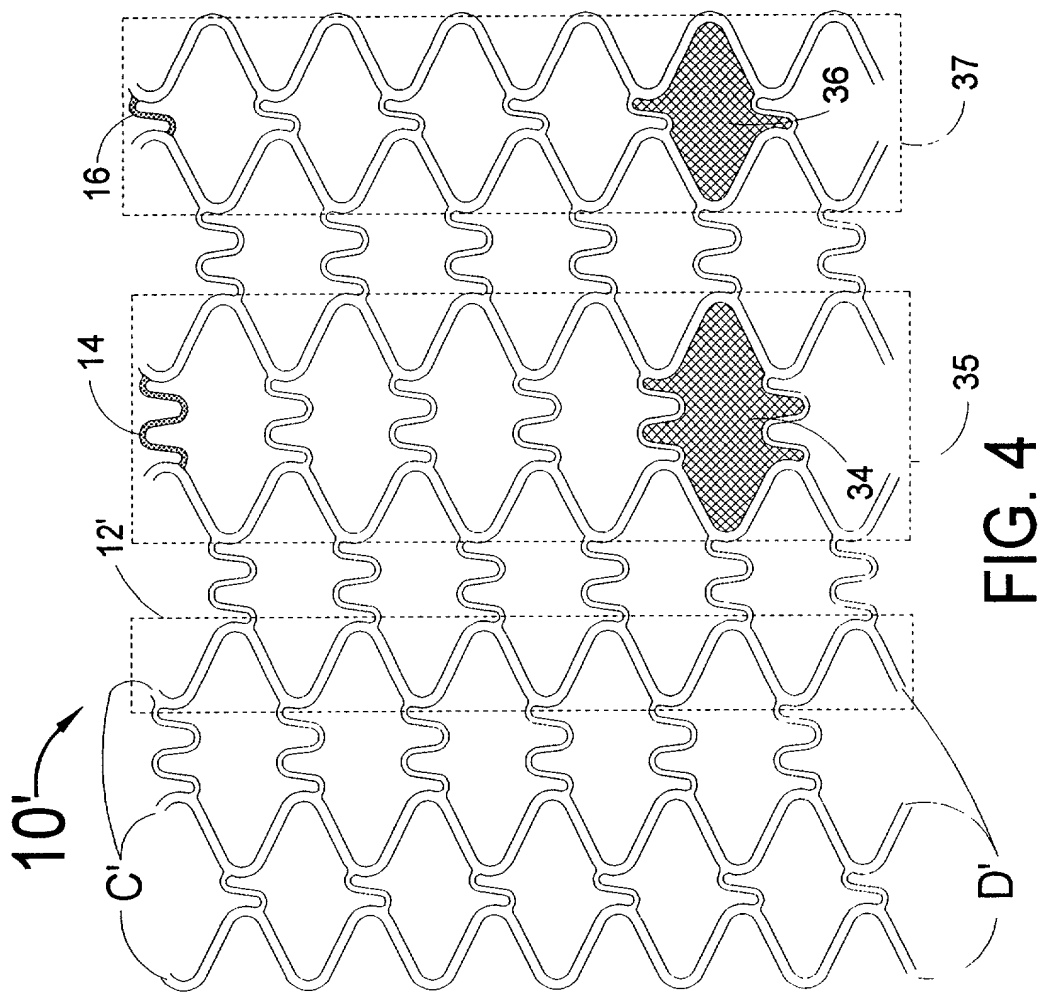


FIG. 1



3
G.
F



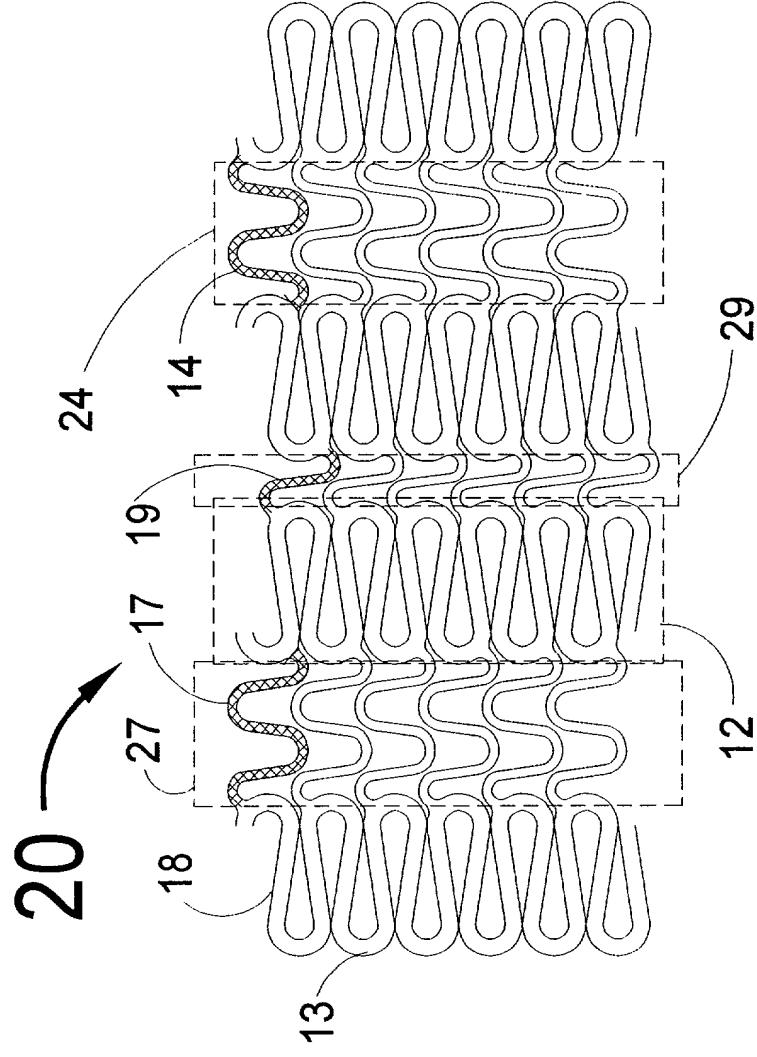
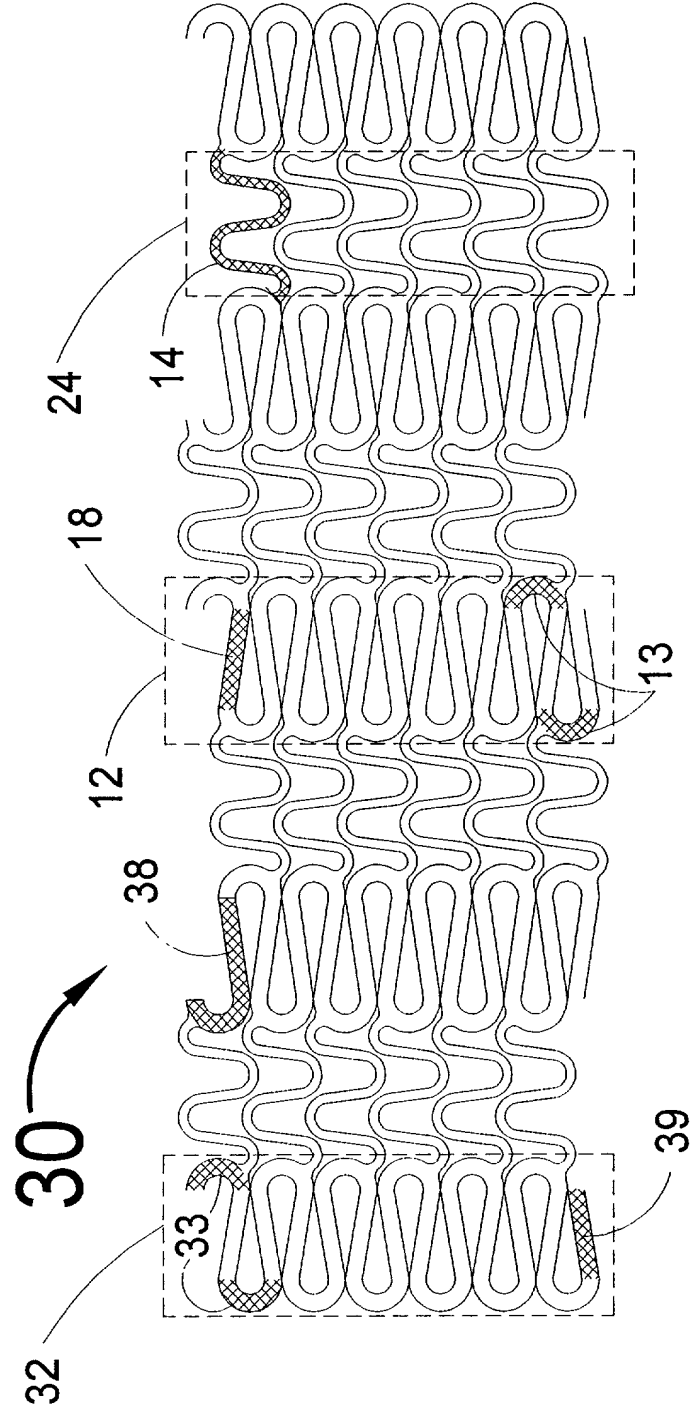
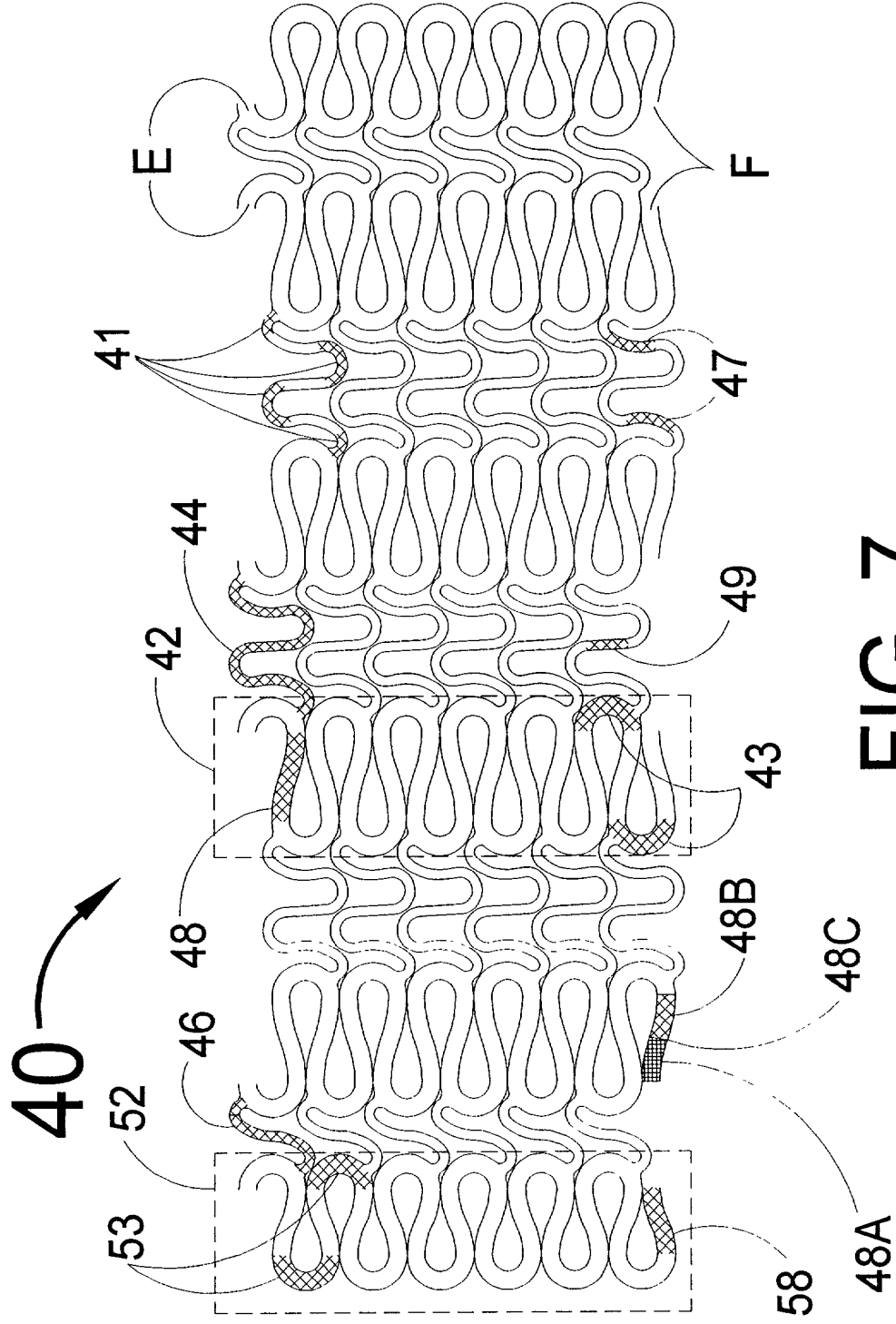


FIG. 5



6. G
F



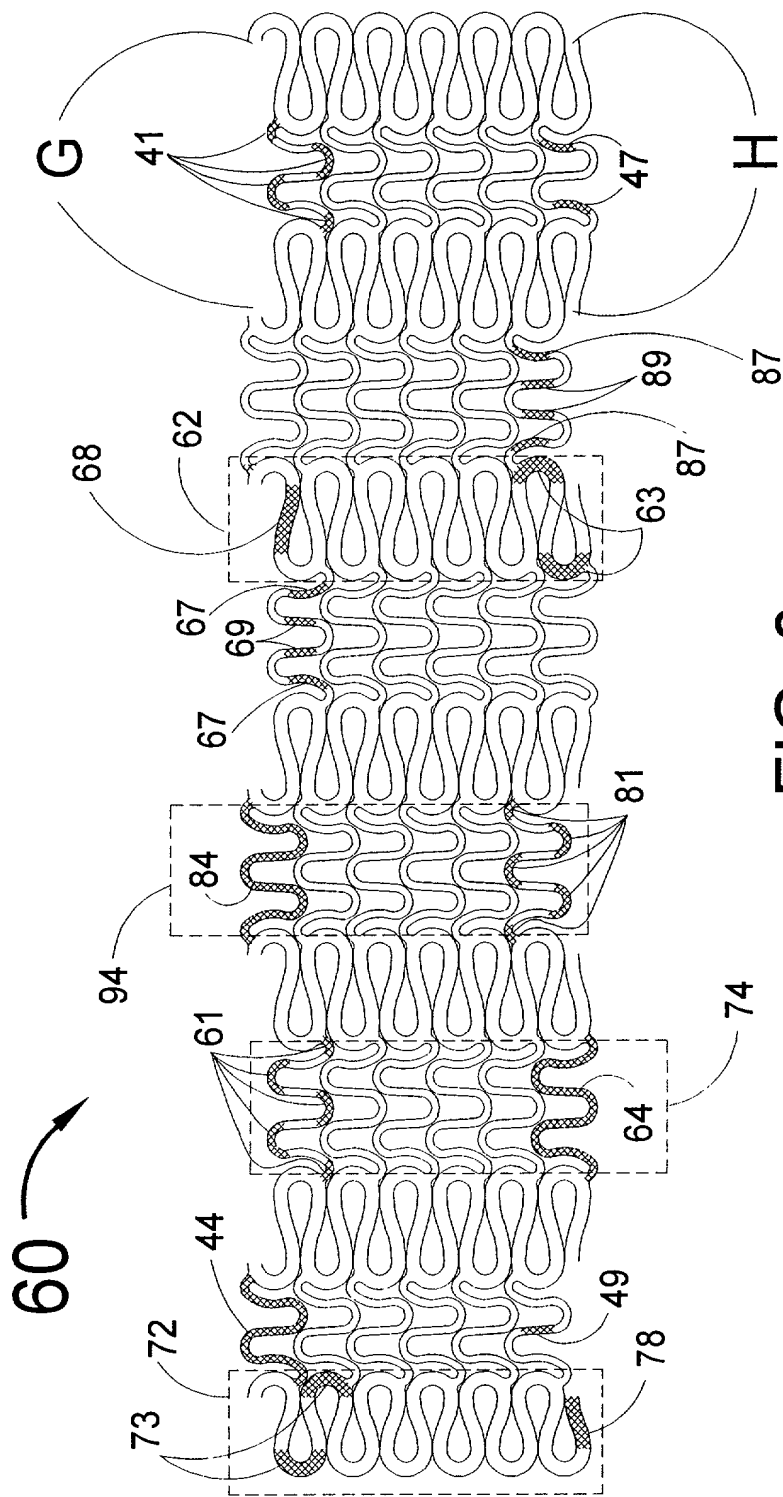


FIG. 8

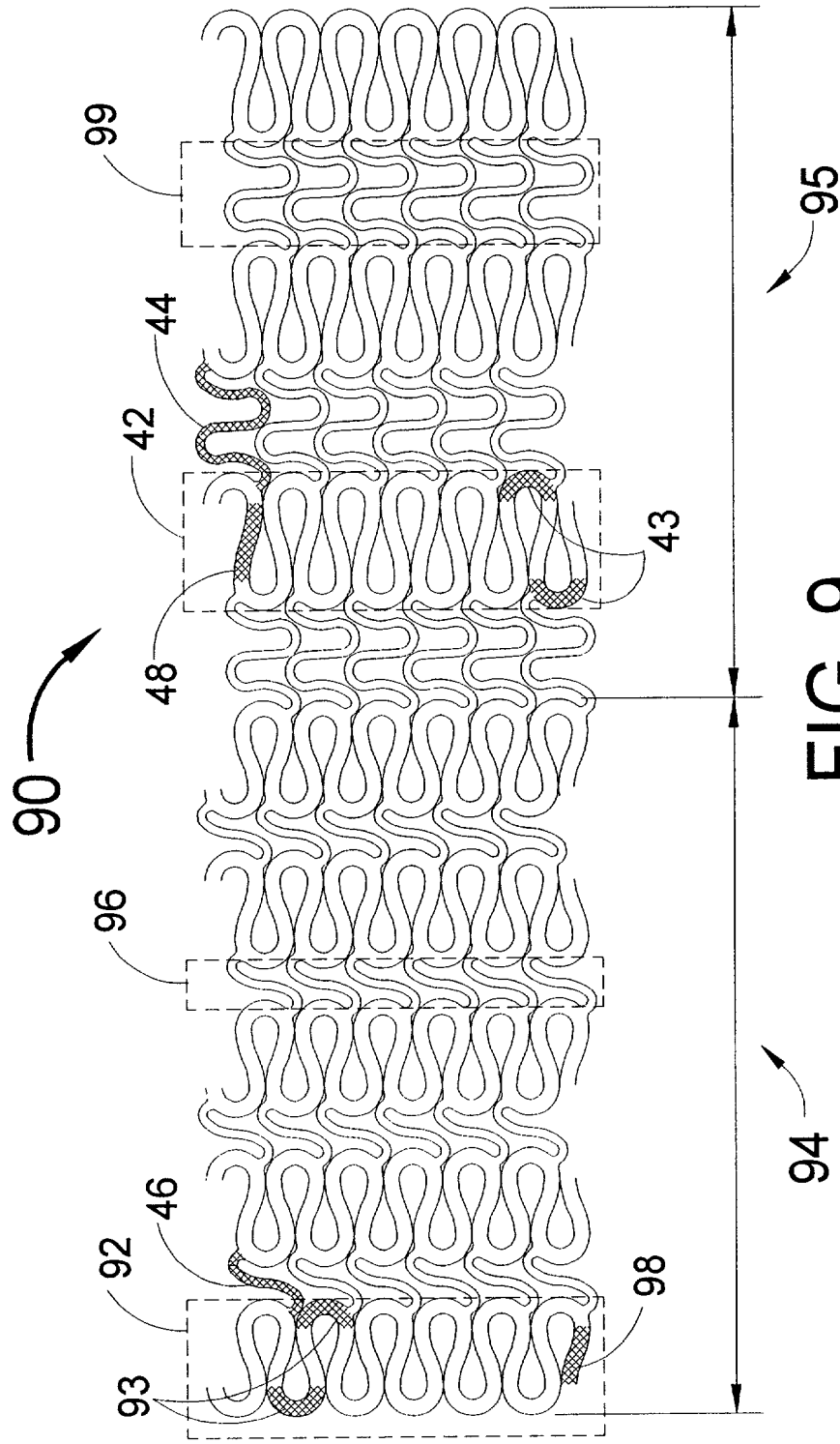


FIG. 9

DECLARATION, POWER OF ATTORNEY AND PETITION

As the below named co-inventors, we hereby declare that we verily believe we are the original and first joint co-inventors of the subject matter which is claimed and for which a patent is sought on the invention entitled: LOW PROFILE RADIOPAQUE STENT WITH INCREASED LONGITUDINAL FLEXIBILITY AND RADIAL RIGIDITY which is attached hereto.

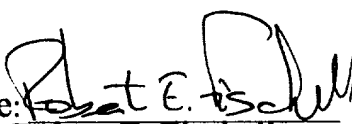
We hereby state that we have reviewed and understand the contents of the attached specification and claims.

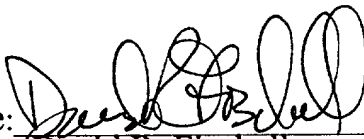
We acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).

We hereby appoint Robert E. Fischell, a co-inventor as our attorney, with full power of substitution and revocation to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

We hereby declare that we are a citizens of the United States of America and that the address and residence for each of us are one and the same and are stated below under our names.

We hereby declare that all statements made herein of our own knowledge are true and that statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issued thereon.

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Date: _____

DECLARATION, POWER OF ATTORNEY AND PETITION

As the below named co-inventors, we hereby declare that we verily believe we are the original and first joint inventors of the subject matter which is claimed and for which a patent is sought on the invention entitled: LOW PROFILE RADIOPAQUE STENT WITH INCREASED LONGITUDINAL FLEXIBILITY AND RADIAL RIGIDITY which is attached hereto.

We hereby state that we have reviewed and understand the contents of the attached specification and claims.


We acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).

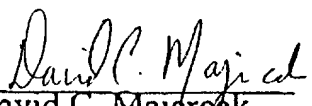
We hereby appoint Robert E. Fischell, a co-inventor as our attorney, with full power of substitution and revocation to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

We hereby declare that we are citizens of the United States of America and that the address and residence for each of us are one and the same and are stated below under our names.

We hereby declare that all statements made herein of our own knowledge are true and that statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issued thereon.

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